United States
Environmental
Protection Agency

EPA Science Advisory
Board (1400F)
Washington, DC

EPA-SAB-CASAC-05-001
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# EPA's Fourth External Review Draft of Air Quality Criteria for Particulate Matter

*A Peer Review by the*
*Clean Air Scientific Advisory Committee*
*Particulate Matter Review Panel*

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**
**WASHINGTON D.C. 20460**

**OFFICE OF THE ADMINISTRATOR**
**SCIENCE ADVISORY BOARD**

October 4, 2004

EPA-SAB-CASAC-05-001

Honorable Michael O. Leavitt
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Subject: Clean Air Scientific Advisory Committee (CASAC) Particulate Matter (PM) Review Panel's Ongoing Peer Review of the Agency's *Fourth External Review Draft of Air Quality Criteria for Particulate Matter* (August 2003)

Dear Administrator Leavitt:

EPA's Clean Air Scientific Advisory Committee (CASAC), supplemented by expert consultants, collectively referred to as the CASAC Particulate Matter (PM) Review Panel ("Panel"), met via a public teleconference meeting on September 20, 2004, to discuss matters related to its ongoing peer review of the two-volume, June 2003 draft document, *Fourth External Review Draft EPA Air Quality Criteria for Particulate Matter* (EPA/600/P-99/002, aD, bD). The current Panel roster is found in Appendix A of this report.

This teleconference meeting was a continuation of the CASAC PM Review Panel's review of the Fourth External Review Draft of the Air Quality Criteria Document (AQCD) for PM in the current cycle for reviewing the National Ambient Air Quality Standards (NAAQS) for PM. The purpose of this teleconference was for the Panel to review the revised Chapter 9 (Integrative Synthesis) of the AQCD for PM, which the Agency provided to the Panel on August 29, 2004.

After an extensive discussion, the Panel concluded that this revised chapter had been sufficiently improved that it could close on Chapter 9, with the understanding that the Agency's National Center for Environmental Assessment (NCEA)-RTP will make further revisions as necessary to address the issues raised both in this report and in the Panelists' individual review comments, which are provided in Appendix B of this report. This action completes the Panel's review of the revised AQCD for PM.

## 1. Background

The CASAC was established under section 109(d)(2) of the Clean Air Act (CAA or "Act") (42 U.S.C. 7409) as an independent scientific advisory committee, in part to provide advice, information and recommendations on the scientific and technical aspects of issues related to air quality criteria and NAAQS under sections 108 and 109 of the Act. Section 109(d)(1) of the CAA requires that EPA carry out a periodic review and revision, where appropriate, of the air quality criteria and the NAAQS for "criteria" air pollutants such as PM. The CASAC, which is administratively located under EPA's Science Advisory Board (SAB) Staff Office, is a Federal advisory committee chartered under the Federal Advisory Committee Act (FACA), as amended, 5 U.S.C., App.

EPA is in the process of updating, and revising where appropriate, the AQCD for PM as issued in 1996. A detailed history of this current, ongoing review is contained in the Background section of the CASAC PM Review Panel's report on this subject from the public meeting held in Research Triangle Park (RTP), NC, on November 12-13, 2003 (EPA-SAB-CASAC-04-004, dated February 18, 2004). The Panel's most recent report on this topic (EPA-SAB-CASAC-04-008, dated August 16, 2004) was prepared following the public meeting held on July 20-21, 2004. Both of these documents can be found on the EPA Web Site at: http://www.epa.gov/sab.

## 2. CASAC PM Review Panel's Ongoing Review of the Revised Chapter 9 of the *EPA Air Quality Criteria for Particulate Matter (Fourth External Review Draft)*

The Panel commends the NCEA staff for the revisions that resulted in a shorter and clearer synthesis of the information. This version of Chapter 9 was greatly improved over the prior version. There are some remaining issues that will be described in this report and will need to be addressed in the final set of revisions.

The description of the science with respect to $PM_{2.5}$ and to a reasonable extent $PM_{10}$ is well presented, but the information regarding $PM_{10-2.5}$ is not yet as clearly articulated. There is the potential for confusion because there are instances when the use of "PM" can be ambiguous in terms of the size fraction being considered. As part of this discussion, it will be useful to provide the rationale for the continuing use of $PM_{2.5}$ rather than other possible cut-points for fine particles.

There is relatively limited information on $PM_{10-2.5}$, and those limits need to be made clear. $PM_{10}$ is not an appropriate substitute for $PM_{10-2.5}$ since it is possible that some of the adverse health effects of $PM_{10}$, most notably annual mortality, reflect only the $PM_{2.5}$ effects and that the coarse mode particles add little to health risk. This issue and the data addressing it need to more clearly be brought out in the document. It would be useful to reduce the discussion of $PM_{10}$ and make a clearer distinction in terms of extent of information on the various fractions.

Another area of concern was the discussion of thresholds that is focused on $PM_{10}$ data yet any standards would involve $PM_{2.5}$ or $PM_{10-2.5}$ or both. The position taken by the Agency is that "available studies do not provide strong evidence of a clear threshold for the relationship between PM concentration and mortality" (p. 9-42) instead of the more accepted way of characterizing dose-response relationships. A more appropriate wording of this statement on

page 9-42 would be: "The available evidence does not either support or refute the existence of thresholds for the effects of ambient PM on mortality." Also, the discussion should recognize that "exposure-response relationships" for one indicator, such as $PM_{10}$, may or may not be applicable to other indicators. The treatment of thresholds is one of the most important drivers of PM risk estimates. Thus, due attention to this matter is most appropriate.

As part of the discussion of Figure 9.4, a short description is needed of what is included in this figure such as the single values for results from the National Morbidity, Mortality, and Air Pollution Study (NMMAPS) and the Canadian Eight Cities Study, as well as appropriate references to the fuller discussion of these results in Chapter 8.

The Panel felt that the modifications to the welfare section were well done. However, it will be useful in future discussions of ecosystem effects for the Agency to clearly address the cumulative nature of ecosystem responses so that new approaches can be considered to ensure the protection of terrestrial and aquatic ecosystems

It would be useful to include a clear statement to the effect that there is a well-defined linear relationship between $PM_{2.5}$ concentration and observed light extinction. We suggest wording such as provided in the comments of Dr. Warren White (see Appendix B, page B-39).

Finally, it would also be helpful if the 2001 to 2003 $PM_{2.5}$ monitoring data could be summarized in Section 9.1.2.

There are a number of editorial and minor scientific issues that are provided in the individual panelists' comments. The Panel does not see any of these issues as major problems and believe they can be addressed with relatively limited modifications to the existing draft. We are pleased that we have been able to complete the review and achieved closure on the AQCD for PM and look forward to working with the NCEA staff on the first external review draft of the air quality criteria document for ozone and other photochemical oxidants in the near future. As always, the CASAC PM Review Panel wishes the Agency well in this very important endeavor.

Sincerely,

***/Signed/***

Dr. Philip K. Hopke, Chair
Clean Air Scientific Advisory Committee

Appendix A – Roster of the CASAC Particulate Matter Review Panel

Appendix B – Review Comments from Individual CASAC Particulate Matter Review Panelists

# Appendix A – Roster of the CASAC Particulate Matter Review Panel

## U.S. Environmental Protection Agency
## Science Advisory Board (SAB) Staff Office
## Clean Air Scientific Advisory Committee
## CASAC Particulate Matter Review Panel*

**CHAIR**

**Dr. Philip Hopke**, Bayard D. Clarkson Distinguished Professor, Department of Chemical Engineering, Clarkson University, Potsdam, NY

Also Member: SAB Board

**CASAC MEMBERS**

**Dr. Ellis Cowling,** University Distinguished Professor At-Large, North Carolina State University, Colleges of Natural Resources and Agriculture and Life Sciences, North Carolina State University, Raleigh, NC

**Dr. James D. Crapo**, Chairman, Department of Medicine, National Jewish Medical and Research Center, Denver, CO, and Chief Executive Officer (CEO) of Aeolus Pharmaceuticals, Inc.

**Dr. Frederick J. Miller**, Vice President for Research, CIIT Centers for Health Research, Research Triangle Park, NC

**Mr. Richard L. Poirot**, Environmental Analyst, Air Pollution Control Division, Department of Environmental Conservation, Vermont Agency of Natural Resources, Waterbury, VT

**Dr. Frank Speizer**, Edward Kass Professor of Medicine, Channing Laboratory, Harvard Medical School, Boston, MA

**Dr. Barbara Zielinska**, Research Professor, Division of Atmospheric Science, Desert Research Institute, Reno, NV

**CONSULTANTS**

**Dr. Jane Q. Koenig**, Professor, Department of Environmental Health, School of Public Health and Community Medicine, University of Washington, Seattle, WA

**Dr. Petros Koutrakis**, Professor of Environmental Science, Environmental Health, School of Public Health, Harvard University (HSPH), Boston, MA

**Dr. Allan Legge**, President, Biosphere Solutions, Calgary, Alberta

**Dr. Paul J. Lioy**, Associate Director and Professor, Environmental and Occupational Health Sciences Institute, UMDNJ - Robert Wood Johnson Medical School, NJ

**Dr. Morton Lippmann**, Professor, Nelson Institute of Environmental Medicine, New York University School of Medicine, Tuxedo, NY

**Dr. Joe Mauderly**, Vice President, Senior Scientist, and Director, National Environmental Respiratory Center, Lovelace Respiratory Research Institute, Albuquerque, NM

**Dr. Roger O. McClellan**, Consultant, Albuquerque, NM

**Dr. Gunter Oberdorster**, Professor of Toxicology, Department of Environmental Medicine, School of Medicine and Dentistry, University of Rochester, Rochester, NY

**Dr. Robert D. Rowe**, President, Stratus Consulting, Inc., Boulder, CO

**Dr. Jonathan M. Samet**, Professor and Chair, Department of Epidemiology, Bloomberg School of Public Health, Johns Hopkins University, Baltimore, MD

**Dr. Sverre Vedal**, Professor of Medicine, National Jewish Medical and Research Center, Denver, CO

**Mr. Ronald White**, Research Scientist, Epidemiology, Bloomberg School of Public Health, Johns Hopkins University, Baltimore, MD

**Dr. Warren H. White**, Visiting Professor, Crocker Nuclear Laboratory, University of California - Davis, Davis, CA

**Dr. George T. Wolff**, Principal Scientist, General Motors Corporation, Detroit, MI

**SCIENCE ADVISORY BOARD STAFF**

**Mr. Fred Butterfield**, CASAC Designated Federal Officer, 1200 Pennsylvania Avenue, N.W., Washington, DC, 20460, Phone: 202-343-9994, Fax: 202-233-0643 (butterfield.fred@epa.gov) (Physical/Courier/FedEx Address: Fred A. Butterfield, III, EPA Science Advisory Board Staff Office (Mail Code 1400F), Woodies Building, 1025 F Street, N.W., Room 3604, Washington, DC 20004, Telephone: 202-343-9994)

* Members of this CASAC Panel consist of:

a. CASAC Members: Experts appointed to the statutory Clean Air Scientific Advisory Committee by the EPA Administrator; and

b. CASAC Consultants: Experts appointed by the SAB Staff Director to serve on one of the CASAC's National Ambient Air Quality Standards (NAAQS) Panels for a particular criteria air pollutant.

# Appendix B – Review Comments from Individual CASAC Particulate Matter Review Panelists

This appendix contains the preliminary and/or final written review comments of the individual members of the Clean Air Scientific Advisory Committee (CASAC) Particulate Matter (PM) Review Panel who submitted such comments electronically. The comments are included here to provide both a full perspective and a range of individual views expressed by Panel members during the review process. These comments do not represent the views of the CASAC PM Review Panel, the CASAC, the EPA Science Advisory Board, or the EPA itself. The consensus views of the CASAC PM Review Panel and the CASAC are contained in the text of the report to which this appendix is attached. Panelists providing comments are listed on the next page, and their individual comments follow.

**Panelist** **Page #**

# Dr. Ellis Cowling

## Cowling Comments on Chapter 9 of the 2004 PM Criteria Document

This newly revised chapter is now very close to closure in my opinion. The much improved organizational structure and even more carefully formulated conclusionary statements bring this chapter very close to fulfilling the promise of its title – Integrative Synthesis.

I hope the mostly editorial comments listed below for section 9.3 -- dealing with PM-Related Welfare Effects where I have some special competence -- will help NCEA staff put the final touches on a generally very good redraft of a very complex concluding chapter for this Criteria Document. This should be possible to achieve before the mandated deadline of October 29, 2004. This revised chapter should provide the integrative synthesis of scientific background for equally careful policy analysis and interpretation that should serve the nation well over the next few years.

I was particularly pleased that the Critical Loads concept, the desirability of a visibility-related Secondary Standard for PM, and the Global Climate Change dimensions of the PM management problems are all dealt with fairly and with reasonable thoroughness. The discussion of increased circulation of reactive forms of nitrogen and its many and varied -- sometimes beneficial and sometimes detrimental -- effects on ecosystem health, productivity, and stability -- was very well done, although some editorial and other changes such as those suggested below will make for further improvement.

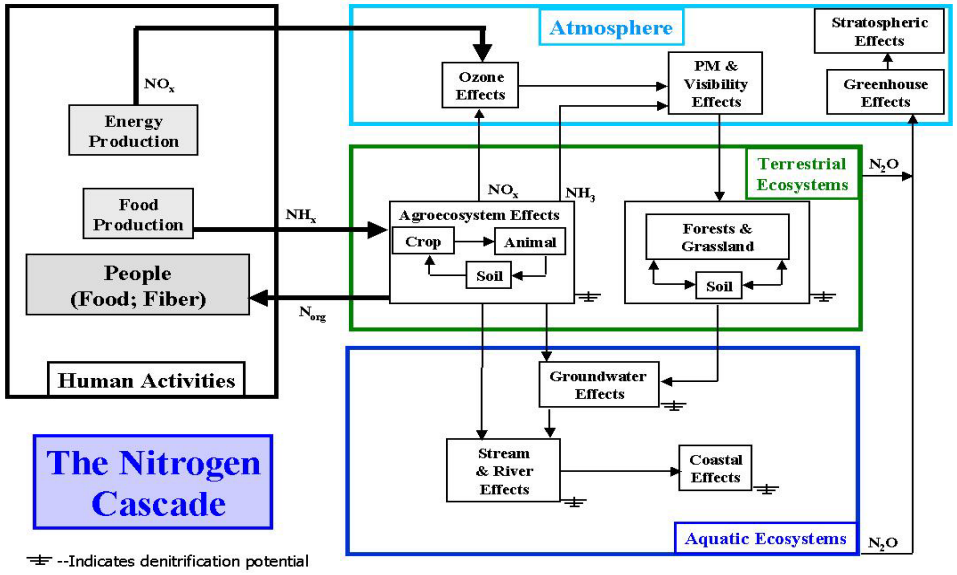
1) Page 9-91 line 16 – John Sienfeld's name is misspelled.

2) As indicated in my earlier comments to Chairman Hopke on August 2, 2004, it was disappointing to find no tables or figures in Chapter 9 dealing with any of the four major PM Related Welfare Effects.

The discussion on page 9-92, lines 15-20 would be improved greatly if one of Molenar's "simulated photographs" of regional haze were included on this page.

Also, the Nitrogen Cascade discussion on pages 9-98 and 9-97 would be greatly enhanced by including the original figure of this Cascade as shown below:

Figure 6. The nitrogen cascade illustrates the movement of human-produced reactive nitrogen (Nr) as it cycles through environmental reservoirs in the atmosphere, terrestrial ecosystems, and aquatic ecosystems (Galloway and Cowling, 2002).



3) Page 9-92, line 30 – What is meant by "special areas."

4) Page 9-93, line 27 – Better to say "In addition, similar "acceptable" and "not acceptable" threshold determinations …" rather than "In addition, similar threshold determinations …."

5) Page 9-94, line 6 – Subscript $_{2.5}$ ; lines 8 and 16 – change "levels" to "concentrations"; line 13 – add "Phoenix, AZ, Lake Tahoe, CA, and State of Vermont" after "Denver, CO."

6) Page 9-95, line 2 – better to hyphenate "site-specific"; line 3 – change "different stressors in PM deposition" to "different chemical constituents in deposited aerosols"; line 29 – add "sulfur and phosphorus" after "nitrogen".

7) Page 9-96, line 2 – omit "being developed"; line 5 – change "component" to "specific chemical constituent"; line 26 – change "of nitrogen via the nitrogen cycle controls" to "of biologically active forms of nitrogen controls"; line 28 – after "roots," add "and by foliar absorption through leaves,"; line 29 – change "(bacteria, blue-green algae)" to "(including bacteria and free-living blue-green algae)"; lines 29-30 – omit last sentence.

8) Page 9-97, line 14 – after "$NH_3$" add "mainly for use as fertilizers"; line 27 – change "get" to "are"; line 28 – add "are" after "and".

9) Page 9-98 – see suggestion 2 above.

10) Page 9-99, lines 8, 13, 17, 19, 20, and 21 – change "nitrogen" to "Nr"; line 9 – omit "background levels (nitrogen loading)"; line 13 – add "accumulation" after "nitrogen".

11) Page 9-100, lines 2, 6, 8, 10, 11, 14, 16, 19, 20, 23, 29, 31 – change "nitrogen" or "N" to "Nr"; line 23 – add "amounts of" after "increased".

12) Page 9-101, lines 1, 2, 10, 22, 24, and 31 – change "nitrogen" to "Nr".

13) Page 9-102, line 2 – change "nitrogen" to "Nr"; lines 14 and 17 – change "acidic" to "acid"; line 12 – add "other" before "acidifying"; change "reduced" to "decreased".

14) Page 9-103, line 1 – change "acidic" to "acid"; lines 8 and 11 – change "nitrogen" to "Nr"; lines 9-10 – change "there is still insufficient data available" to "insufficient data are available".

15) Page 9-104, line 4 – change "(wet, dry, occult)" to "(wet, dry, and occult (cloud and fog deposition)".

16) Page 9-105, line 9 – change "effects on radiation receipts" to "effects on incoming solar radiation"; line 10 – add "still" before "poorly"; line 11 change "reducing" to "decreasing".

17) Page 9-107, line 12 – change "particle" to "PM"; line 13 – change "reduces" to "decreases"; change "reduce" to "decrease"; change "exposure level" to "exposures"; change "perceived " to "observed".

# Dr. James D. Crapo

Review of Chapter 9 PM AQCD Crapo

General Comments:

I have reviewed the revised Chapter 9. In general this chapter is thorough. It is accurate and clearly written. I have concerns regarding two general areas which would require some restructuring and small modifications of the document.

1. Assessment of Health Effects of Fine vs. Coarse Mode Particulates

The document presents strong data showing that there are significant health effects associated with $PM_{2.5}$ and with $PM_{10}$. It contains numerous statements as to the limited availability of data regarding $PM_{10-2.5}$. The critical decision element here is whether or not coarse mode particles need to be separately regulated. The coarse mode particles are substantially different particulates with regard to their formation, characteristics, and distribution. It is likely that they are substantially different in health effects and there appears to be regional differences in these particles that may have direct impacts on health risk. A critical question is whether or not $PM_{10}$ can be used as a surrogate for health effects of coarse particles. I agree with the court ruling which suggests that regulation of coarse mode particles should be based on data directly on coarse mode particles, not including the $PM_{2.5}$ fraction as would occur if one used $PM_{10}$. It is possible that the adverse health effects of $PM_{10}$ reflect only the $PM_{2.5}$ effects and that the coarse mode particles add little to health risk. This issue and the data addressing it need to more clearly be brought out in the document. I would recommend that the discussion of the $PM_{10}$ data be reduced and focused more on the regional differences in $PM_{10}$ health effects and whether or not under certain circumstances $PM_{10}$ can be used as a surrogate for health effects of the coarse mode particulates. The concern is whether or not health effects of the $PM_{2.5}$ fraction dominate the results from $PM_{10}$ and thus $PM_{10}$ would not provide a rational basis for separately regulating coarse mode particles. The discussion of the $PM_{10-2.5}$ results should be expanded to better address this issue and lay a foundation for a conclusion to either call for more research or consider regulation of coarse mode particles.

Figures 9.4 and 9.5 would suggest that the health effects of $PM_{10}$ are the same as or greater than that found with either $PM_{2.5}$ or $PM_{10-2.5}$. The discussion suggests that the most robust definition of adverse health effects is with $PM_{2.5}$. On page 9-28, lines 17-19, it states that if the effect estimates were presented per microgram/$m^3$ for each PM mass measure, the effect estimates for both $PM_{2.5}$ and $PM_{10-2.5}$ would be larger than those for $PM_{10}$. It seems to me that this is the most important subject this document should address. I would recommend changing Figures 9.4 and 9.5 to express the effect estimates per microgram/$m^3$ for each PM mass measure.

Finally, the discussion of the cut point of 2.5 as noted on pages 9-19 through 9-21 ignores the data presented at the last CASAC meeting showing that the obvious cut point between fine and coarse mode particles is one micrometer. The document should contain a more accurate description of the advantages and disadvantages of a 2.5 micron cut-off and a frank discussion of

the advantage or disadvantage of a 1 micron cut point. The current document fails to even address this issue.

2. Threshold and the use of a linear concentration-response model with no threshold.

I strongly disagree with the discussion of concentration-response relationships contained in Section 9.2.2.5. I know of no chemical for which the biologic health effects show a linear concentration no-threshold model when adequately and properly studied. It is extremely unlikely that particulates truly exhibit a no-threshold model. The problem is in extrapolating to zero from highly variable data at relatively high concentrations. The high variability of the data helps create a good fit for a linear model. The current data does not suggest that there is no threshold. In the absence of solid reproducible data at very low concentrations, we should not conclude that there is no threshold. We should, instead, criticize the data for not providing evidence of where that threshold is. We should not say that we do not provide strong evidence of a clear threshold, rather, it should be stated that we do not have adequate studies to define the threshold.

I believe the above issues can be easily addressed and provide a more scientifically rigorous document that would better enable the next stage of decision making for setting air quality standards.

# Dr. Frederick J. Miller

## Chapter 9. Integrative Synthesis

General Comments

This version of Chapter 9 is significantly improved over the version reviewed at the July 2004 CASAC meeting. The organization and flow of the chapter is good. With due attention to comments offered by CASAC reviewers, I believe this chapter does not need to be seen again by CASAC.

The authors have done a better job of summarizing current knowledge about the health effects of $PM_{2.5}$ than they have for $PM_{10-2.5}$. The case for $PM_{10-2.5}$ is presented more as "riding on the coattails of PM in general" rather than an effective presentation of the state of our knowledge about the potential for $PM_{10-2.5}$ to cause health effects or to exacerbate existing disease. Since the courts have ruled that $PM_{10}$ reflects double jeopardy if one has separate standards for $PM_{2.5}$, the integrated synthesis chapter needs to do a better job of treating $PM_{10-2.5}$ directly and to that extent, a lessening of the space devoted to describing $PM_{10}$ effects would be warranted.

The other area still of concern to this reviewer has to do with the material concerning thresholds. All of the discussion of thresholds is focused around $PM_{10}$ data yet any standards would involve $PM_{2.5}$ or $PM_{10-2.5}$ or both. The position taken by the Agency is "available studies do not provide strong evidence of a clear threshold for the relationship between PM concentration and mortality" (p. 9-42) instead of the more accepted way of characterizing dose-response relationships. If that were done, the statement on p. 9-42 would be "available studies do not provide strong evidence that there is not a threshold for the relationship between PM concentration and mortality." Currently, Chapter 9 comes across as a clear bias by the Agency in favor of no threshold models. Yet, for the curves in Figure 8-30, which form the basis of a discussion of thresholds, 7 of the 9 curves are clearly nonlinear to the naked eye, as noted in previous comments by this reviewer. How thresholds are or are not treated will be the single most important driver of PM risk estimates. Thus, due attention to this matter is most appropriate. In my specific comments below, threshold aspects are further commented upon.

Specific Comments

p. 9-2, l. 28 For the syntax of this sentence and grammar, the decreases should not be listed as negative values.

p. 9-5, l. 3 It would be useful to make reference back to the chemical composition chapters for additional information on the coarse mode composition.

p. 9-12, l. 2 The discussion of the inclusion of high wind blown dust events is an important aspect that needs to be brought forward in the final interpretation of potential $PM_{2.5}$ effects as how such days are treated can have an impact on the statistical form of the standard.

p. 9-15 Figure 9-2 is misleading. The x axis is labeled in intervals and yet the data are connected by a series of line segments. To more accurately reflect the interval nature of the data, a bar graph should be used.

p. 9-15, l. 9 It would be worth clarifying what is meant by non-ambient components of personal exposure so that the reader understands these are indoor generated materials and are not the ambient components that have penetrated into the house as a function of the penetration factor.

p. 9-20, l. 18 Why the distinction thoracic coarse particles as indexed by $PM_{10-2.5}$? The particles in the size range between 2.5 and 10 have significant deposition throughout the respiratory tract and for many of the particle sizes have a maximum in deposition in the head. The bottom line is that there is no value in using nomenclature to imply thoracic coarse particles compared to non-thoracic coarse particles. This nomenclature is a holdover from the use of $PM_{10}$ where the concern was for particles capable of penetrating to the thorax, but the use of this modifier at this point is questionable to this reviewer.

p. 9-27, l. 7 The statements about $PM_{10-2.5}$ confidence intervals relative to hospitalization for cardiovascular effects is worded in a biased manner by indicating that some but not all of the associations are statistically significant. A more accurate representation of the data would be to say that very few of the associations are statistically significant.

p. 9-28, l. 17 The conclusion or statement here seems counterintuitive because another way to phrase the result is that the whole is less than the sum of its part in that $PM_{10}$ effect estimates are indicated to be less than the combined effect estimates for either of the two fractions comprising it. Do the data really support the statement here? Or are we seeing a lack of precision due to decreased statistical power from most of the studies that looked at a component of $PM_{10}$ compared to those studies that only used $PM_{10}$ as the indicator variable?

p. 9-35, l. 13 The conclusion here, while correct, is somewhat misleading in that the statement is a generality in terms of PM, as opposed to the various subdivisions of PM (i.e., $PM_{2.5}$ or $PM_{10-2.5}$) that would have to be used in revising any existing standards or proposing new ones.

p. 9-39, l. 30 Don't we know the direction of bias in this case for the single day lag with the largest effect? If so, this should be indicated because currently the reader does not know if the bias is to increase or decrease the estimate of the true effect.

p. 9-40, l. 25 The statement here is very important and should carry forward relative to the averaging time for any particular indicator variable as it may relate to desired protection against a specific adverse health outcome.

p. 9-41, l. 11 This paragraph comes across as a weak attempt to justify the assumption of a no threshold model for PM effects. The basic tenet is that it would be difficult to establish a population threshold due to individual differences in susceptibility or other aspects and that it would be difficult to interpret an observed population threshold biologically. One could just as easily approach this paragraph by saying that it is difficult mathematically to demonstrate convincingly that a clear threshold does not exist in population studies. This latter statement of the situation is more in line with the concepts of sigmoidal curves for dose response whereby extremely low dose effects may be approached with low dose linear approximations, but in the case of $PM_{10}$ would be counter indicated because the Agency is arguing there is no nonlinearity in the overall response curve, a position that is not supported by the curves contained in Figure 8-30. Also worth noting is the fact that the Clear Air Act does not require protection of every single individual, thereby acknowledging that individual thresholds do in fact exist, but that sensitive subpopulations that can be identified need to be protected against adverse health outcomes. It is difficult for this reviewer to see how the Agency can argue both sides of the coin.

p. 9-54, l. 5 The aggregation of the smaller particles in the accumulation and Aitken modes is a red herring relative to re-suspended vs. real world ambient human exposures. This is comparing apples and oranges and needs to be reworded because the surface area comparison that is alleged here has no basis in reality of making re-suspended material equivalent to original ambient inhaled material.

p. 9-55, l. 2 Don't the authors mean combustion and non-combustion source particles?

p. 9-55, l. 11 The authors should refer to this reviewer's comments relative to page 7-166, l. 10 of Chapter 7 whereby it was previously commented on the caveats that are needed for the particular comparisons being made. These comments were submitted as part of the July review of Chapters 7 and 8 of the PM Criteria Document. Taking into account those comments, this paragraph needs to be modified.

p. 9-74, l. 1 Given the results of Figure 9-5 concerning hospital admissions for respiratory disease for the $PM_{10-2.5}$ fraction, this statement that coarse thoracic particles are likely contributing to exacerbation of various respiratory conditions is worded too strong. In the opinion of this reviewer, the case for $PM_{10-2.5}$ effects is a weak one given the limited data available and the nature of their results.

p. 9-81, l. 20 The section on vulnerability appears to be a late addition as well as a late aspect of interpretation for PM effects. The variables discussed in terms of socioeconomic are typically accounted for in models that adjust for these as potential concomitant variables and other aspects such as greater exposure near roadways would be reflected in dose response considerations. Thus, the rationale for this section is not immediately apparent. Workplace exposure or tobacco smoking can be considered as vulnerability factors. The introduction to this

section should clarify why only some vulnerability factors are being discussed here.

p. 9-89 Section 9.3 on welfare effects still lacks an integrative punch. This reviewer cannot tell the increment in knowledge, whether there is concern that secondary standards should be changed because new evidence is available for effects at lower levels, whether the 6–8 hour averaging time on visibility should carry forward, and the list goes on. In short, as opposed to the health effects described in the integrated synthesis chapter, the welfare effects are described in much broader detail and without any clear implication for the relevance of new findings in relationship to PM welfare effects. Thus, the imbalance in the bottom line for health vs. welfare is a striking difference to this reviewer.

# Dr. Frank Speizer

Review of Chapter 9 submitted by Frank Speizer

I think this is a much improved chapter on which I am prepared to sign off on. I have taken the 5 basic questions outlined in section 9.2 and offered for each a brief commentary. Mostly the suggestions can be ignored as I am sure they will all be taken up again in the Staff paper. Were minor changes are suggested staff can consider them in the context that they might offer some further clarity.

The Section 9.2 synthesis of PM-related health effects information is organized around five key issues:

(1) Consideration of fine and coarse thoracic particles as separate subclasses of PM pollution, taking into account atmospheric science, exposure, and dosimetry information;

Most of the discussion of the particle subclasses is theoretical. The limited data that discuss penetration and mode accumulation are important. Although there are regional data what is not pointed out is that there are relatively few data sets that can provide relationships between the modes for broad regions of the US. It is not likely that the early chapters create such a catalogue. This should be indicated as a potential weakness, particularly as related to setting national standards.

(2) Assessment of strengths and limitations of the epidemiological evidence for associations between health effects and fine and coarse thoracic PM within the mix of ambient air pollutants;

The presentation seems convincing that there is a consistent (enough) relationship for total mortality, cardiovascular mortality and respiratory mortality related to PM10 and PM2.5 to affirm the findings for 1996. The assessment of PM10-25 is clearly hampered by the lack of sufficient independent measures of the course fraction to assess the separation from PM2.5. However, the studies that are presented do indeed show positive associations, although generally with wider confidence intervals and generally overlapping the null. An issue that might be discussed further is the appropriateness of using 25ug for PM2.5 and PM10-2.5 and 50ug for PM10. Is there a more accurate delta that could be considered in the comparison? (I think this is covered in chapter 3 and some words might be transferred here.

(3) Integration of epidemiological and experimental (e.g., dosimetric and toxicological) evidence supporting judgments about the extent to which causal inferences can be made about observed associations between health endpoints and various indicators or constituents of ambient PM, acting alone and/or in combination with other pollutants.

Section 9.3.2.1 seems to be generically written for the most part and is a useful general description of what the potential for how to interpret. It seems to me too long, but I would not

change it at this point. In general when the specific outcomes are presented there is a reasonable correlation between the toxicological results and the epidemiological findings. This is particularly true for cardiovascular endpoints where the 4 candidate mechanisms are discussed in detail along with the appropriate animal and in vitro studies, with rather short term insults more highly correlated. Respiratory symptoms and pulmonary function appear to be correlated with toxicological findings of slightly longer durations of exposure than cardiovascular effects (several hours vs. minutes). Probably need to indicate in greater detail that there are few if any [toxicological] studies of PM10-2.5. Although there are additional toxicological studies that link mutagenecity with particles, since we really do not have a model for lung cancer it seems to me that this needs to be admitted up front and then indicate that the mutagenecity is the closest we can get. With regard to fetal development the epidemiology data are so weak and inconsistent that it seems inappropriate to try to show consistency with toxicological studies. In fact the section simply does not mention any [toxicological] studies, and my suggestion would be to simply leave it out. This is acknowledged on page 9.74, but is mixed up with a susceptibility question with regard to effects in children, which probably belongs in the next section.

4) Characterization of susceptible and vulnerable subpopulations potentially at Increased risk for PM-related health effects;

Good general summary but need to acknowledge that there are insufficient data to say much about particle size and specific susceptibilities.

(5) Discussion of potential public health impacts (including newly emerging evidence for adverse cardiovascular effects) of human exposures to ambient PM in the United States.

At the end of the first paragraph on 9.88 there is a statement that may be true but needs better documentation with more quantification, if that is possible. This will be an important issue to take up in the Staff paper. It is probably ok to leave it as it is here.

Chapt9.cretique0916/04

# Dr. Barbara Zielinska

**Comments on revised Chapters 9 of the PM AQCD** **September 16, 2004**
Barbara Zielinska

In my opinion, this revised version of Chapter 9 is significantly improved over the previous version. The addition of Section 9.1.2 (Trends in US PM Air Quality) provides a proper context for the subsequent discussion of exposures and health effects. I have only a few minor comments:

1. Page 9-4, line 7: analytical limitations are due not only to the polar nature of some of the organic compounds, but also due to the presence of oligomeric and/or polymeric substances in ambient fine PM (i.e. biopolymers, humic-like substances).
2. Page 9-10, l. 23-25. The sentence "Fine particles include metals, black or elemental carbon, organic carbon (primary PM) and sulfate, nitrate, ammonium and hydrogen ions, and organic compounds (secondary PM)" doesn't make sense. Organic compounds constitute organic carbon and they could be both primary and secondary. The composition of fine PM was discussed in Section 9.1.2, so it is redundant here (and not correct).
3. Page 9-10, l. 27. The composition of coarse PM was also discussed in Section 9.1.2 on page 9-5, line 3-9. To say that the composition of coarse PM includes only primary minerals and organic materials is not correct. It looks like these sections were written by two different persons.
4. Page 9-16, Table 9-2 and p. 9-20, l.10: The infiltration factor for accumulation mode particles depends on ventilation conditions of a building.
5. Page 9-46, l. 12-13: I'm not sure what authors are trying to say in this sentence: "PM exist as a complex air pollution mixture that includes other pollutants" Which other pollutants?
6. Page 9-49, l. 20-22: A prolonged storage of filters in inappropriate conditions leads not only to volatilization of semi-volatile material, but also to chemical alterations of reactive compounds and possible growth of mold, bacterial contamination, etc.
7. Page 9-57, l. 5: Secondary components of submicron aerosol include also organic species, not only inorganic.
8. I support Warren White suggestion to substitute two paragraphs on page 9-90 – 9-91.

## Dr. Jane Q. Koenig

Comments on revised Ch 9
9-18-04
Koenig

It is gratifying to see that the document has been shortened although certainly not by 60%.

I agree with most of the comments that the other reviewers have presented. I do want to second the point that James Crapo raised about PM1.0. We spent considerable time discussing this in July and I do believe the CD needs to include a summary of that discussion.

I support Warren's additions re visibility.

I think the discussion on indicator, averaging time, numerical level and statistical form belong in the Staff paper. Although I certainly agree with Roger that this chapter cant be labeled a summary!! (114 pages!!).

I am in favor of including PM10-2.5 data (as few as they are). I do not believe the health studies allow us to ignore the coarse fraction.

I apologize for being so late with my remarks. Time flies!

# Dr. Petros Koutrakis

## Chapter 9

**Integrative Synthesis**

Reviewer: Petros Koutrakis

The Integrative Synthesis chapter is now more concise and reads well. I am satisfied with the quality of this chapter. Below please find a few minor comments:

**9.1.2** - Page 8, Line 21:
I am surprised that the CD relies mostly on the Lipfert paper. I was expecting that there is more information on this important issue.

**9.1.2** - Page 9, Line 19:
As I said in my previous review, this issue has been a little bit exaggerated. Also this is not the place to comment on particle toxicity.

**Table 9 – 2:** Page 21:
Table 9-2 gives a nice comparison of the three modes. My only comment is that the infiltration factors can vary with home ventilation. So they are not always high or low etc.

**9.2.2.3** – Page 44, Line 5:
Climatic conditions should also be included, since they affect the home infiltration rates, air condition use etc.

**9.2.3.1.1** – Page 54, Line 8:
CAPs studies have not used overly high exposures.

**9.2.3.1.1** – Page 55, Line 2:
I guess you are talking here about the fine particle concentrators because the ultrafine can concentrate ultrafine particles.

**9.2.3.2.2**. – Page 69, Line 29:
To my knowledge there are one or two studies showing ultrafine effects. I think the word "a few" is very generous here.

**9.2.5.2**. – Page 87, Line 28:
Fix typo, PM10-2.5

# Dr. Allan Legge

PM CD, August/2004, Revised Chapter 9
Allan Legge
September 17, 2004

Review Comments:

The revisions to Chapter 9 ('Integrative Synthesis') have been well done and better reflect a balance in the available scientific information. Section 9.3.2 Effects of Ambient PM on Vegetation and Ecosystems, has drawn together the key pieces of our current knowledge and understanding. It is time to reach closure. That being said, it is hoped that the 'Staff Paper' picks up on the cumulative nature of ecosystem responses and the need for a new approach to ensure the protection of terrestrial and aquatic ecosystems.

The following are two specific comments:

1. Page 9-95, line 11.

This should read: "These effects were usually the result …."

2. Paged 9-102, Section 9.3.2.2.2 Acidification from PM Deposition, para. 2.

The important role of Ca in ecosystems is noted. The specific reference to Bondietti and McLaughlin (1992) on line 24 relates to Ca in wood. This is fine as per the text. An additional and more current reference with respect to Ca in ecosystems is found in McLaughlin and Wimmer (1999).

McLaughlin, S.B. and Wimmer, R. 1999.
Calcium physiology and terrestrial ecosystem processes. Tansley Review No. 104.
New Phytologist 142: 373-417.

# Dr. Paul J. Lioy

Integrative Synthesis
Chapter 9 - PM Criteria Document
Fourth External Review draft

Comments of Dr. Paul J. Lioy

General

The Agency has made a very good effort in addressing my concerns, and those presented by others. At this point in time we should close on the Chapter, and approve the Criteria Document. I have a few suggestions for improvement.

1. Page 9.4 There are values presented on abundances for some of the trace elements. To be consistent, the agency needs to consider adding some information, e.g. > or < X ug/$m^3$ for the compounds or compound classes mentioned on lines 11 through 18.

2. Page 9.43, Line 14, The paragraph correctly states that there is a link between short term exposure, hours to days, and cardiovascular and respiratory mortality and morbidity. However, on pages 9.23 etc, the statements about short term effects < day are vague, if non-existent. Please introduce a sentence or two to support this important observation. The current version of Chapter 9 does have a statement related to peak exposures on page 9-39 in subsection 9.2.2.4 – Temporality and the Question of Lags. This should be supported by a more specific statement on or about 9.23.

3. General: Exposure – response relationships for cardiovascular and other effects over periods that are on the order of hours have been observed in research studies. These results require the development of sampling protocols that will collect and analyze continuous PM data at critical urban locations in the US. Thus, a statement to this end is required somewhere in the chapter. Clearly, there will be more studies designed to reduce uncertainties about the relationship between short term exposures and cardiovascular disease. Consequently, a national data base should be developed for PM found in the ambient air of US cities to establish the frequency and PM concentration ranges for periods of 2 to 8 hours. Consideration should be given primarily to continuous measurements of $PM_{2.5.}$

September 16, 2004

# Dr. Morton Lippmann

**REVIEW COMMENTS**

**M. Lippmann**

**Chapter 9 of PM AQCD**

**August 2004 Draft**

## General Comments

This revised draft has recognized and successfully addressed the significant concerns of the Panel members at the last review session. In particular, the text on pp. 9-8 and 9-9 and on pp. 9-20 and 9-21 provides the technical and policy bases for choosing $PM_{10}$ and $PM_{2.5}$ cut sizes for PM NAAQS that was lacking in the previous draft. Also, the text on p. 9-10 now addresses the importance of particle bound water (PBW), and Figure 9-1 on p. 9-11 provides a much better summary representation of the typical volume modes of the ambient aerosol and their size distributions.

The paragraph on p. 9-9 (lines 16-22) on the study opportunities created by routine $PM_{2.5}$ monitoring for improved understanding of the associations between ambient air PM and human health should be amplified by a forward looking statement such as: "We can anticipate that the Speciation Site network and the increasing availability of continuous monitors for $PM_{2.5}$ will provide further opportunities to identify PM components and their sources most responsible for PM health effects, and for elucidating the role of peak exposures within a day that may cause acute responses."

The issue of identifying a population threshold from observational studies, which is addressed on p. 9-41 remains a concern to scientists who deal primarily with toxicological study data. It may be advisable to refer, in this section on concentration-response relationships, to explicitly refer to the following section on natural experiment studies, which generally indicate

that significant reductions in ambient pollution are associated with improvements in health status. Also, this section should introduce the Kunzli et al. (2001) concept of frailty, which is cited in Section 9.2.5.2 (on p. 9-88) as a factor that could account for the lack of a threshold in population studies.

**Specific Comments**

| Page | Line(s) | Comment |
|---|---|---|
| 9-9 | 11 | insert "the health risks of" before "thoracic" |
| 9-32<br>9-34 | 10-12<br>30-31 | These statements improperly ignore the 10 year prospective study of children in Southern California. |
| 9-58 | 6 | insert "to" before "have" |
| 9-71 | 18 | insert "mortality" before "data" |

# Dr. Joe Mauderly

Review of Chapter 9 of PM CD
Mauderly

**General Comments**

Overall, this is a reasonable integrative synthesis. I think that with minor editing, it can be accepted. I like the approach that avoids citing lots of references. I'd still like a last section in which the key advances since the last CD, and those considered most critical to the standard, are listed clearly in bulletized form.

**Specific Comments**

P 9-1, L 21: "Remaining uncertainties that remain" is redundant.

P 9-2, L 25: Not clear whether this is geographical national average or average population exposure.

P 9-3, L 8: Same question as above.

P 9-3, L20-21: The point about different monitoring methods needs explaining – a short, single-sentence expansion would suffice.

P 9-8, L 12-13: This sentence doesn't make sense. Of course particle size is the basis for distinguishing between fine and coarse collection, but I don't think that's what you mean.

P 9-10, L 19: "PBW" is already defined.

P 9-12, L 17: Use the definition, "PBW".

P 9-30, L 17: It should be "the magnitude**s** of the associations **are** –".

P 9-39, L 12-15: This sentence isn't a useful summary for the section. The reader perceives that you are trying to make some distinction between "numerous locations" and "various places", which, I don't think, is your point. Your point either isn't clear or this is a very unremarkable summary sentence. It doesn't say anything.

P 9-47, L 26: It should be "—area **are** summarized –".

P 9-49, L 14-22: Probably should also mention here the possibility for biological growth on the samples during uncontrolled storage (bacteria, molds).

P 9-49, L 28: It should be "—CAPs **varies** across—".

P 9-53, L 30: Delete "exercising" – the sentence as written is redundant.

P 9-54, L 7-10: This isn't the important point. The more important point is that you can't do the simulation even with high doses. Yes, you can get a "dose" of PM surface into the lung, but it wouldn't bear any resemblance to the surface encountered by humans, or the relationship of surface to mass. It is very misleading to suggest that jacking up a dose of larger PM to simulate the surface dose of smaller PM is a legitimate comparison. The notion itself is corrupt.

P 9-55, L 2: The sentence isn't clear. Combustion source PM is part of ambient PM. What's the point you are trying to make?

P 9-55, L 11-20: Unless the exposure materials were shown to be identical (and I don't recall that they were), this is not a legitimate comparison. It suggests that all CAPs is alike, which it isn't. Including this comparison is misleading.

P 9-55, L 24: Have you defined "MO"?

P 9-56, L 3: It should be "Comparison**s** in Chapter 7 **of** rodent –".

P 9-56, L 28-29: This sentence is so full of jargon as to be obscure. How is the reader supposed to know what "metastable species" are, or what "dead" components are? If there is an important thought here, put it in English.

P 9-62, L 6: Two animal studies, one human experimental exposure, and one epidemiology study have shown Factor VII to be <u>decreased</u> in relation to exposure to PM. What is your evidence that it should be increased, other than our incorrect preconceived notions of a few years ago?

P 9-62, L 15-16: Several locations are cited below. What does "within a given location" mean?

P 9-63, L 28-30: What in the world could "metal-associated ROFA" mean? Presumably you mean ROFA containing high concentrations of metals. You have already defined the abbreviations given in line 30.

P 9-64, L 10-11: The sentence implied that fibrinogen was increased at 69 $\mu g/m^3$. I doubt that was the case. We tried to correct sentences like this in earlier chapters.

P 9-65, L 23: I think you have a stray hyphen here.

P 9-68, L 18: "Follow-up" is usually hyphenated.

P 9-70, L 18-19: As I recall, the 1996 AQCD did not state that bioaerosols were unlikely to "contribute to" effects. I think the statement was that they were unlikely to "account for" PM effects. That's two different things. In fact, that language carried over into the first draft of this CD, and was corrected. The main point is that now, it is considered likely that biomaterials do contribute to PM effects.

P 9-70, L 27-28: We need to focus on different components. That doesn't necessarily mean from different regions. "Regions" is the flyer here – the focus should be on components. The fact that different regions have different average compositions is true, but not the relevant point here. It would be unreasonable to suggest that the key way to get at the importance of different components would be to study different regions. Region is a very crude surrogate for composition.

P 9-72, L 10: Tumorigenic" is misspelled.

P 9-77, L 21-24: Two currently-used models ought to be included in this list: experimental coronary artery blockage, and apo E atherosclerosis-prone mice.

P 9-78, L 2-3: Two "roles" are redundant.

# Dr. Roger O. McClellan

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September 22, 2004

## Review Comments on Revised Chapter 9: Integrative Summary (August 2004)

The August 2004 draft of Chapter 9, Integrative Summary of the Particulate Matter Criteria Document, is improved over the earlier version of the Chapter. However, in my professional judgment, the Chapter still does not reach the standard I would like to see the U.S.E.P.A. reach in summarizing the current scientific information that will inform the Administrator's decisions on the four elements of a National Ambient Air Quality Standard for Particulate Matter; (1) indicator, (2) averaging time, (3) numerical level, and (4) statistical form. Nonetheless, recognizing the court-ordered time constraints faced by the Agency, I reluctantly concur in a decision for CASAC to close on the Chapter and move on to consideration of the Staff Paper. As reflected in my comments below, in my professional judgment, the Integrative Summary over-states the certainty of the scientific evidence relevant to re-affirming or revising a $PM_{2.5}$ standard and very substantially over-states the certainty of the scientific evidence to be considered in making a decision on the potential promulgation of a $PM_{10-2.5}$ standard.

I offer the following comments for consideration by the EPA staff:

## General Comments

1. The present draft is not an adequate "Integrative Summary." It is excessively long and, thus, is clearly not a summary. In some places it comes close to integrating the available data but the integration is obscured by excessive detail. I suspect a hard-nosed science editor could readily reduce the length of the Chapter by a factor of two, most of the reduction could occur by reducing the discussion on pgs 9-46 to 9-73 which has limited bearing on the setting of a NAAQS for any PM indicator.

2. The CD, including this Chapter, is still handicapped by the artificial division between the science covered in the 1996 CD and the more recent evidence. The NAAQS for any PM indicator must be based on all the available science irrespective of when it was developed and published. The document, and Chapter, would be easier to read and understand if it focused on all the important science. The present CD, including this summary, labors in many places to include an excessive amount of new details. Most of the new details presented on pages 9-46 to 9-73 will not inform the setting of a standard and could be readily summarized in a table and a few pages of text.

3. The "Integrative Summary" is not a balanced presentation of the science that will inform the setting of the NAAQS for PM. The tone in many places attempts to justify past actions in the setting of the $PM_{2.5}$ standard. In other places, it strives to provide a basis for promulgating a standard based on a $PM_{10-2.5}$ indicator. This chapter does not always summarize critical uncertainties in key data analyses and interpretations that were ultimately added to earlier chapters. The resulting tone in this chapter reflects a higher degree of certainty in evidence than is warranted.

4. I was pleased to see the inclusion of a section (9.1.2) on "Trends United States PM Air Quality." I suggest that the time period covered be extended by both considering information pre-1992 (see the ACS study and Harvard Six Cities study for some early time period monitoring data) and for 2001-2003.

5. I was pleased to see the section (9.2.5.1) on health statistics although I would not have titled it as "Magnitude of Susceptible Groups." A title such as "Baseline Health Statistics" would be more appropriate. I urge that this specific section be moved to the Introduction as Section 9.1.3 right after the "Trends in United States PM Air Quality." Tables 9.4 and 9.5, which consider morbidity indices, should be complemented by a Table on mortality, i.e. causes of death. It is important to recall that data on increased mortality from cardiovascular and respiratory disease associated with increased levels of ambient PM 9see Figure 9.4) plays a major role in decisions on the NAAQS for PM. In discussing Tables 9.4 and 9.5 and the new table on causes of death, a new paragraph should be added indicating the dominant role of cigarette smoking in causing cardiovascular and respiratory disease. I was reminded of this again today when I noted the local freeway billboard showing 318,000 deaths in 2004 through September 20$^{th}$ attributed to cigarette smoking.

6. Section 9.2.1 (Fine and Coarse Particles as Separate Sub-classes of PM Pollution) should be rewritten with a stronger and more accurate historical orientation. The revision should more clearly indicate the direct linkage between what has been monitored and the conduct of subsequent epidemiological investigations. In short, epidemiological studies can only be conducted using the indicators that have been monitored. Over time these measurements have progressed from metrics such as smog days to black smoke to total suspended particulate (TSP) matter to $PM_{10}$ to $PM_{2.5}$ to $PM_{10-2.5}$ and particle number. $PM_{1.0}$ and $PM_{15}$ were only monitored for a brief period of time in the 1980s. This section needs to be forthright in acknowledging that EPA's regulatory compliance monitoring program (TSP → $PM_{10}$ → $PM_{2.5}$) has dictated the kind of data available for conduct of epidemiological studies. The lack of monitoring data on $PM_{1.0}$ and $PM_{10-2.5}$ and the related lack of epidemiological data for these indicators is a direct result of past EPA actions. One might hypothesize that $PM_{1.0}$ and $PM_{10-1.0}$ would be the better indicators for fine and coarse particles than $PM_{2.5}$ and $PM_{10-2.5}$. However, this will remain a hypothesis until monitoring data and related epidemiological results on these indicators are available and the findings compared to epidemiological evaluations of $PM_{2.5}$ and $PM_{10-2.5}$ at the same locations.

7. In many places the document uses what I term a "PM blanket" approach, analogous to the blanket Linus in the cartoons, or my kids, carried around. In short, when the evidence on a particular indicator does not exist or is uncertain the authors attempt to make up for it by relating evidence from another PM indicator or resort to describing PM evidence in general. This approach is inappropriate. The evidence for each indicator needs to be considered independently. It is not appropriate to attempt to make up for a lack of evidence for the $PM_{10-2.5}$ indicator by using evidence on $PM_{2.5}$.

8. The Chapter would benefit from a concluding section on the key science that will inform decisions on the four elements, as noted above, of a NAAQS for PM. Beyond consideration of the indicators as noted above, the Chapter would benefit from a more thorough presentation of the evidence on the relationship between ambient concentrations ($PM_{10}$, $PM_{10-2.5}$ and $PM_{2.5}$) and increased adverse health effect outcomes at levels typically found in the U.S. today. The failure of the "Integrative Summary" to adequately address this critical issue abdicates consideration of this matter to the Staff Paper. This is a science matter that should have been more adequately covered in the CD and especially this Chapter. The issue of ambient concentration-response to relationships is a matter that goes well beyond the cursory coverage of

"thresholds" in the CD and this Chapter. The CD, and this Chapter, also fails to address the scientific information that under-girds consideration of a statistical form for the NAAQS for PM.

Specific Comments

Pg 9-1, line 25: Insert a paragraph noting the science reviewed in this chapter is intended to inform decisions on the four key elements of a National Ambient Air Quality Standard (NAAQS): (1) indicator, (2) averaging time, (3) numerical level, and (4) statistical form. In this last chapter of the CD which, up to this point, is largely an exposition on the "world of PM and its health and welfare effects" needs to acknowledge that the CD has a specific purpose-inform decision on the four elements of the NAAQS for PM.

Pg 9-8, line 23 – pg 9-9, line 4: This long sentence conveys the view that a conscious decision was made to select $PM_{2.5}$ μm as a size cut in the last review over selection of some other size metric. This is ridiculous. The decision had been made much earlier when EPA, in my view, inappropriately selected $PM_{2.5}$ μm as the cut-point in the design of new monitoring instrumentation. If a science-based approach had been taken, monitoring data would have been collected on both $PM_{1.0}$ μm and $PM_{2.5}$ μm cut-points and epidemiological studies conducted on both indicators. This would have provided a basis for the CD considering both $PM_{1.0}$ and $PM_{2.5}$ μm cut-points. EPA should not attempt to revise history and ignore its traditional "regulatory compliance" orientation to collecting monitoring data. Unfortunately, the monitoring data available for conducting epidemiological studies is that collected under the "regulatory lamp post."

Pg 9-11, line 4: 1996 PM AQCD, not 1966

Pg 9-12, line 19: This sentence may not be technically correct as I noted in my comments in the last draft of Chapter 9. Yes, formaldehyde and other volatile compounds may become associated with particles. However, this particle associated fraction may not be as biologically significant as the associated gas phase concentrations of the chemicals. By and large this is an important hypothesis that should guide future research. However, the available data are so limited that it is of limited value in setting a NAAQS for PM. Moreover, the hypothesis does not warrant discussion more than once in this summary chapter.

Pg 9-15, line 8 on: The discussion needs to emphasize the substantial geographic differences in "infiltration factors" as influenced by temperature, humidity and local ventilation practices.

What is true for Boston is certainly not true quantitatively for other cities, for example, Birmingham, AL and San Diego, CA.

Pg 9-16, line 20: Insert "calculated" as in "The calculated fractional depositions --- " Later it should be noted that detailed actual measured deposition values are available primarily over the size range of 0.5 to 5 μm.

Pg 9-19, line 16: The sentence will confuse many readers. The earlier discussion (Table 9.1) emphasizes that the fine mode consists of an ultrafine and accumulation mode. The "story line" needs to be consistent.

Pg 9-20, line 5-9: This sentence is confusing and adds nothing. The behavior of ultrafine and coarse particles is fundamentally different. The strained linkage here is inappropriate and creates confusion.

Pg 9-20, line 20 on: This paragraph needs to be rewritten to more clearly convey that what is important is the "integrated" deposition of all particles within a given mode (i.e. ultrafine, fine and coarse), not whether there are differences in the deposition of particles of a specific size, such as 0.1, 0.5, 1.0, 2,0, 3.0, 5.0 or 10.0 μm. The tone of the text suggests that mathematical modelers are losing touch with biological reality.

Pg 9-23, line 4-6: This very important sentence should be rewritten – "the impact of ambient air pollution exposure on these outcomes ~~may be~~ is very small in comparison to that of other risk factors (e.g. smoking and diet)." I find it curious that the EPA staff can be so conclusive elsewhere about PM effects but here when it draws a comparison with the well-established major risk factor, smoking, it uses the word may, apparently to heighten concern for PM effects and reduce concern for smoking effects.

Pg 9-26, line 7: Figure 9-4 and the related discussion here is MISLEADING. The data from Dominici *et al* (2003a), the National Mortality and Morbidity Air Pollution Study on 90 (88?) cities, and the Burnett *et al* (2003) study of 8 Canadian cities are presented as single estimates in contrast to all the other single city estimates. The result is to mislead the reader as to the consistency of the observations. The fact of the matter is that *"Some of the associations between $PM_{10}$ and total mortality are positive and some are statistically significant. However, many associations are not statistically significant especially when cities are studied using the same methodology."* This needs to be acknowledged in the text and also reinforced by including a figure illustrating the NMMAPS results for multiple

cities. In my opinion, the NMMAPS results represent a critical finding that should inform decisions on the NAAQS for PM. It is not scientifically appropriate to focus on the composite estimate to the exclusion of the individual city estimates. If for policy or ideological reasons the decision is to ignore the individual city estimates, EPA needs to clearly articulate the rationale for the approach.

Pg 9-26, line 8: The Chapter would convey a more scientifically credible tone if it would simply described the evidence for a given size fraction. This serves as a good example in which the discussion of $PM_{2.5}$ starts by relating it to $PM_{10}$. The approach taken is one that again tries to wrap every size fraction in the "PM blanket." The authors should describe the evidence and avoid attempting to lead the reader.

Pg 9-26, line 9: The same is true for $PM_{10-2.5}$, although here the "PM blanket" is even more moth eaten. Leave out the first sentence. The evidence is – *"There are a few effect estimates for $PM_{10-2.5}$, most are positive and similar in magnitude to those reported for $PM_{2.5}$ and $PM_{10}$, but few reach statistical significance."*

Pg 9-26, line 11-14: This represents another example of "bundling" or using the "PM blanket." In earlier sections, apparently written by a different author, the document emphasizes the differences between the various indicators. Now the authors reverse course and elect to bundle $PM_{10}$ and $PM_{2.5}$ together. THE DATA FOR EACH INDICATOR, $PM_{10}$, $PM_{2.5}$ AND $PM_{10-2.5}$, NEEDS TO BE DESCRIBED SEPARATELY. It is obvious that $PM_{2.5}$ and $PM_{10-2.5}$ are a part of $PM_{10}$. However, if we did not have some evidence of differences it would be appropriate to just use a single indicator, $PM_{10}$.

Pg 9-27, line 8: It would be more accurate to end – *"and most of the associations are not statistically significant."*

Pg 9-28, line 10-13: I submit that this statement concerning $PM_{10}$ effects in the western United States is an unproven hypothesis. It should be stated as such or much more substantial evidence should be presented for the <u>western</u> United States. It is important to recall the diverse nature of the western United States ranging from Los Angeles to Houston to Dallas to Albuquerque to Phoenix to Seattle to Salt Lake City. This is a blatant example of how the CD tries to selectively relate science to apparently meet some pre-conceived regulatory notations. In this case, the apparent attempt is to provide the basis for a $PM_{10-2.5}$ standard

based on alleged associations with mortality and morbidity. In this case, the science does not exist.

Pg 9-30, line 15-30: In this summary paragraph the authors again attempt to wrap $PM_{10-2.5}$ in the "PM blanket." It would be more scientifically accurate to *say "there is limited scientific evidence for an association between $PM_{10-2.5}$ ambient concentrations and mortality."*

Pg 9-31, line 25-31: It is unfortunate that the recent paper from the Southern California school children study cannot be cited in the CD. My read of it is that it identifies an association between elevated air pollution (using multiple pollutant indices) and retarded lung growth. However, the authors were careful to not focus on PM to the exclusion of other pollutants.

Pg 9-32 to 9-42: This entire section needs to be rewritten and each topic addressed on an individual indicator basis. The present style of writing in which the authors sometimes describe the evidence for PM and at other times for $PM_{10}$, $PM_{2.5}$ or $PM_{10-2.5}$ is misleading. The nature of the evidence for each PM indicator is different and, in some cases, there is every reason to hypothesize that the nature of the evidence for each indicator will be different. An example is concentration-response relationships.

Pg 9-33, line 27 (Confounding): The section on confounding is written with a bias toward emphasizing a PM effect and downplaying the effects of other pollutants.

Pg 9-36, line 19: The use of phrases like – "would be expected" serve as a tip-off that the authors are ready to offer a conclusion that would be better stated as a "hypothesis." Ultimately, standards are to be set based on scientific conclusions, not scientific hypotheses.

Pg 9-36, line 23 on: The next 3 pages provide a discourse on consistency and variability. In the interest of scientific completeness it would be appropriate to note that some studies that fail to show an association between various PM indices and health outcomes may in fact reflect an absence of a PM effect. Throughout the document, studies that do not show a positive association of a health outcome with a PM indicator or fail to be statistically significant are described as though the effect was there; it just has not yet been found.

Pg 9-41, "Concentration-Response Relationships": This section, which should summarize information that will be key in setting the "numerical level" of any NAAQS for a PM indicator, is totally inadequate and misleading. This section needs to describe the evidence related to the title of the section. It is not adequate to just discuss the "threshold concept."

The discussion needs to acknowledge the limitations in the statistical tools and the data for describing concentration-response relationships at ambient concentrations of $PM_{10}$, $PM_{2.5}$ or $PM_{10-2.5}$ as experienced in most areas of the United States today. This would include linear versus non-linear relationships and not just thresholds.

Pg 9-42, line 4-10: This concluding paragraph is "one-sided." It should acknowledge the difficulty in evaluating ambient concentration-health response relationships for a "weak" risk factor, such as various PM indicators, when ambient concentrations are low. I would argue that if statistically significant associations are not found, as in the case of many cities in NMMAPS that stands as evidence of a "practical threshold." As a scientist I do not understand the unwillingness of EPA to acknowledge that there are areas in the United States today where there may be an absence of a PM effect or, indeed, on air pollution effect.

Pg 9-42, line 14-24: Reverse the flow of the paragraph to correspond with the strength of the evidence starting with $PM_{10}$, then $PM_{2.5}$ and concluding with $PM_{10-2.5}$.

pg 9-43, line 8-13: Eliminate the paragraph.

Pg 9-44, line 7: Why not offer a separate statement on $PM_{10-2.5}$ and let go of the "PM security blanket." For example, – *"There is only very weak and uncertain evidence for an association between $PM_{10-2.5}$ and mortality/morbidity outcomes."*

Pg 9-44, line 13-15: Another blatant attempt to try to rationalize a lack of evidence for $PM_{10-2.5}$ effects. This kind of "pleading" should be avoided in the CD. The CD should lay out the science as it exists, not attempt to re-interpret it to apparently support a regulatory agenda.

Pg 9-45, line 4: To use the word "causal" to modify the "associations" is an over-statement. The epidemiological evidence supports an association with a "weak signal" for $PM_{10}$ and $PM_{2.5}$ related to baseline mortality and morbidity.

Pg 9-45, line 4-11: Describe the evidence for each indicator. DO NOT attempt to cloak $PM_{2.5}$ with $PM_{10}$ evidence or $PM_{10-2.5}$ with $PM_{10}$ or $PM_{2.5}$ evidence. Remember these are <u>different</u> indicators and it is not surprising that the associations between excess risk and ambient concentrations will be different.

Pg 9-45, line 11-12: The one-liner is a bold statement. Give a better description of the nature of the evidence for the association between excess health risk and increased ambient

concentrations of each indicator ($PM_{10}$, $PM_{2.5}$, $PM_{10-2.5}$). DO NOT use the "PM blanket" to dodge this critical issue.

Pg 9-46 to 9-73: This section can be substantially shortened. I recognize that it reports the results of an enormous amount of research. However, calling a "spade a spade" this section only offers modest support for the epidemiological associations between increased ambient concentrations of various PM indicators and an increase in health outcomes. Most of the information could be summarized in one or two tables and a few paragraphs. One paragraph could describe the challenges and experimental limitations of linking the "weak" stochastic signals found in some epidemiological studies with experimental approaches dependent upon relating "deterministic" measures of effects. It could conclude with a statement that the experimental evidence lends support to a causal association between exposure to high levels of some PM indicators and an increase in adverse health outcomes. The nature of the evidence is so fragmentary that it is not always apparent as to how it relates the various indicators. A revision of the section needs to clearly describe the nature of the integrated evidence for the individual indicators, $PM_{10}$, $PM_{2.5}$ and $PM_{10-2.5}$ and especially the latter two indicators since they are likely to be the focus of the NAAQS-PM standard setting. In the scientific communities zeal to focus on $PM_{2.5}$ little attention has been directed to obtaining experimental evidence on the $PM_{10-2.5}$ fraction. This lack of experimental evidence on $PM_{10-2.5}$ needs to be acknowledged in Chapter 9.

Pg 9-54, end of page: It would be appropriate to add – *"Moreover, the extensive modeling results presented in Appendix 7A provide a number of hypotheses for experimental testing. There will be increased confidence in the models and results when additional experimental data are obtained and the models subjected to rigorous validation with new data other than that used to develop the models."*

Pg 9-71, line 18-21: If the 2002 extended ACS analysis is cited as evidence of an association between exposure to fine particles and lung cancer at least a brief mention should be made of the lack of long-term smoking histories in the ACS study. As I recall the smoking history of individuals in the cohort were only ascertained at the beginning of the study. Differential shifts in the various sub-populations such as those from different socio-economic levels could have influenced the outcome.

Pg 9-84, Susceptible Groups: I find it interesting that the authors cannot state the obvious – *"The largest susceptible groups for PM associated effects are cigarette smokers and former smokers. The vast majority of the respiratory and cardiovascular endpoints summarized in Tables 9.4 and 9.5 reflect effects observed in cigarette smokers and former smokers."* I suggest including a paragraph on cigarette smoking trends in the U.S.

## Dr. Günter Oberdörster

To: Drs. Butterfield/Hopke

Review of Chapter 9 of PM Air Quality Criteria Document (G. Oberdörster)

In my view, EPA has responded well to the comments of CASAC. I think the Chapter, although still long, represents a good approach for an integrative summary and, with the additional suggestions made during Monday's conference call, it is ready for closure. Some additional editorial/factual comments/suggestions are as follows:

Page 16, Table 9-2: The infiltration factor for ultrafine particles is described here as "generally low". However, since it is actually high between 60 and 100 nm (see Figure 9-2), I suggest to state "low to high (size dependent)".

Page 20, line 2: I suggest to add "mass" to the word "concentrations" since this statement does not apply to number concentrations.

Page 48, lines 24 through 26: A sentence should be added that such models of compromised animals should be relevant to the human condition as much as possible with respect to the pathophysiology of a specific condition. The first example of a compromised animal model given here, *i.e*., monocrotaline-treated rats, is in my view not a good example for the human condition. Thus, the emphasis on relevancy would be important to point out here.

Page 50, line 9: Although CAPs concentrators can include gaseous co-pollutants, gases will not be concentrated like the particles, so CAPs exposures are still different from the real world.

Page 52, line 14: Emphasize that for *in vitro* studies always several doses should be included and that a "real-world" dose should always be included in such studies.

Page 55, lower paragraph, and page 56, upper paragraph, inhibition of phagocytosis: Overwhelming alveolar macrophages by the amount of PM is very unlikely for ambient particles, this is an overload issue. Also, there will be a compensatory AM influx rather than a decrease in AM numbers. I am also not sure that the differences in inhibition of phagocytosis between humans and hamsters on the one hand and mouse on the other are real, given that primary cells are compared here with a cell line. Also, the smaller size of mouse macrophages *vs*. those of humans should not be of significance for ambient PM exposures, since we are not dealing with overload situations here. Thus, I am not sure that the alleged differences in inhibition of phagocytosis pointed out here are real; at best one could say that there <u>may</u> be differences between species.

Page 80, line 25: Replace "homogeneity" with "regional efficiency".

9/22/04
GO/jh

# Dr. Robert D. Rowe

**September 10, 2004**
**Robert Rowe comments on August, 2004 PM CD Chapter 9.**

Visibility section

- Page 9-93, lines 9-10. I'm not comfortable with the sentence as is – I don't think it makes clear the core issue with the studies is about the exact dollar values (which varies with variations in the method(s) and is not unusual in science). Maybe something more like "Results vary across studies and uncertainties remain about the specific dollar values estimated." The studies can also provide information about whether people believe different levels of visibility impairment are sufficiently adverse to warrant doing something or paying something, which the existing sentence indirectly but inappropriate puts in question as well.

- Page 9-93 lines 13, 14, 26; page 9-94 line 19. "values" is used with the perception/adversity judgment studies in several places. Broadly, the responses are "value statements." However, I worry that here "value" will be confused with monetary valuation. I think phrasing it as "'perceptions and attitudes about visibility impairment,' including what is adverse' (as on page 9-94 lines 10-11) is more precise as to what theses studies provide and that what they provide ties nicely to the concept of adversity in the CAA.

- As noted in the Committee letter, "it would be helpful to indicate the approximate $PM_{2.5}$ mass concentrations that correspond to the various visual range values that are discussed" in the perception/adversity judgment studies.

Ecosystems section. Page 9-95, line 11. Syntax needs editing "These effects were the usually…."

Climate section. Page 9-105, line 2. "impairment" would be slightly preferred to "degradation" for consistency with terminology in the visibility section.

Materials.

- This section relies heavily on 1996 AQCD, which is OK. But, there needs to be a sentence as to why – which is that there has been limited applicable research since that time that fundamentally changes the conclusions, or some such statement to justify not saying a thing about work since 1996 (for example, see climate section page 9-105 line 11). The last sentence (page 9-107 lines 17-20) alludes to the same concept without being explicit.

- Page 107, lines 15-16. This sentence misses several endpoints, as identified in the committee letter. "Available data indicate that airborne particles can result in increases in the frequency of cleaning, maintenance, or replacement of exposed materials ~~surfaces~~, as well as reduced usefulness and enjoyment of injured ~~soiled~~ materials." (Its not just surfaces, its not just soiling, its not just cleaning).

- Page 107, lines 17-20. Its not just perceptions ("perception thresholds of damages and soiling") but both perception and functionality, or welfare impact. For example, upon close

inspection a material may be clearly altered but may have no function or welfare impact requiring cleaning, maintenance or replacement.

## Dr. Jonathan M. Samet

September 17, 2004

To: Phil Hopke

From: Jon Samet

Subject: PM AQCD Chapter 9

Phil, I have read the revised chapter and in general, I find it to be satisfactory and ready for closure. Staff have responded to my concerns on the prior draft, particularly those related to the interpretation of the epidemiological evidence. The chapter is more concise and even readable. I have a few specific comments as follows:

- In discussing $PM_{2.5}$ and $PM_{10-2.5}$, the chapter addresses issues relate4d to composition and dosimetry and covers the scant epidemiological data. The chapter should integrate the information on site of deposition and composition to infer whether different adverse health effects would be anticipated for the two size fractions. This section could be a bit stronger on mechanisms and health outcomes.
- The discussion on pages 9-19 and 9-20 has several confusing elements. How does consideration of the ultrafine mode add to understanding of $PM_{2.5}$ health effects? The comparison of ultrafine and coarse particles on page 9-20 is not helpful and should be deleted.
- At the bottom of page 9-26, having invoked exposure error and other issues, what are the net consequences for interpretation of the evidence? A sweeping concern is raised without follow-up.

# Dr. Sverre Vedal

**PM CD (chapter 9)**
**Sverre Vedal**
**September 20, 2004**

1. General.

This revised draft has dealt with nearly every one of the specific issues I had raised in July about the previous version. I will not detail these here. Any concerns that I have with the chapter, at this point, are largely due to differences in opinion as to how the evidence should be interpreted rather than concerns about fair representation of the findings or about factual errors. Overall, I find the current organization of the chapter to be acceptable, even though I considered the earlier organization around 5 questions to also have been a reasonable approach. The current organization of topics in fact corresponds to the earlier one, but with different topic headings.

2. Consistency of findings.

This discussion of consistency has been expanded and improved, although the main point now seems to be one of explaining why inconsistency is to be expected, rather than maintaining that consistency is present. It is argued, based on figures 9-4 (p.9-24) and 9-5 (p.9-25), that studies with more power generally show more consistently significant effects. While this is probably true, I would point out that for the important outcome of cardiovascular mortality (figure 9-4), studies with less power have generally larger and significant effect estimates. I would drop the argument relating power and statistical significance based on findings reported in the 1996 CD (p.9-38, L16-18). This reliance on the 1996 CD suggests to me, perhaps unfairly, that findings based on studies reported subsequently do not make the same point.

On a small point, chapter 8 of the CD appropriately qualifies the lack of statistical evidence for heterogeneity of effects in NMMAPS by noting the limited statistical power of the test for heterogeneity in this setting; no such qualifying of this conclusion is included here (p.9-37, L7 & 21).

3. Coherence.

The chapter now focuses the discussion of coherence as pertaining to that between the observational findings and the experimental and toxicological findings, which I believe is appropriate. Arguing strongly for coherence based on types observational outcomes is fraught with pitfalls and is probably best avoided at this time.

4. Cohort studies.

I continue to maintain that the relatively strong effect of SO2 in the ACS cohort study should not merely be dismissed as being difficult to interpret due to the fact that SO2 is a precursor of sulfate (p.9-35, L3-4). This finding in the ACS study should have prompted a more thoughtful discussion of residual confounding in the cohort studies, particularly in light of the questionable consistency of findings in the cohort studies as a whole.

# Mr. Ronald H. White

Comments of Ronald White, M.S.T.
Revised Draft Particulate Matter Criteria Document – Chapter 9: Integrated Synthesis
September 20, 2004

## General Comments

This revision of Chapter 9 of the fourth draft Particulate Matter Criteria Document (PM CD) has adequately responded to all of the major issues and editorial changes requested by the CASAC PM panel at its July 2004 meeting. The discussion of particle size, composition and respiratory tract deposition is improved from the previous version, as is the discussion and use of the concepts of consistency and coherence in interpreting the results of health effects studies. The document has been considerably condensed and extraneous discussion and references to specific studies that are not essential to the major points of the document have generally been eliminated. The integration of animal toxicology and controlled human study results with the epidemiological evidence in the discussion of coherence of results and potential biological mechanisms in Section 9.2.3 finally achieves the key objective for an integrated synthesis chapter.

The elimination of Tables 9A1-3 should be reconsidered, however, as they provided important summary information from the key U.S. and Canadian studies on the mortality and morbidity effects estimates associated with daily and long-term PM exposures. The inclusion of information on the mean and range of PM concentrations measured in each study is especially useful in providing a context for the levels of PM associated with the effects estimates. While I appreciate the need to limit the size of Chapter 9 so that it is a readable synthesis of the scientific information, dropping these valuable tables is a case of "penny-wise, pound-foolish". Alternatively, this information could be integrated into the summary tables in Appendices 8A and 8B, though with the result of adding complexity to already dense tables.

With the presumption that only relatively minor editorial changes which are likely to be suggested by the CASAC PM panel as part of the current review will be satisfactorily addressed by EPA in the final version of Chapter 9, I recommend closure for this chapter.

## Specific Comments

Pg. 9-26, Line 6: As there is frequent reference in this and subsequent sections to "more precise" study results, an operational definition for the criteria used (i.e. confidence interval size) to determine which study results are considered "more precise" than others should be included.

Pg. 9-28, Line 17-19: This is an important point that bears further discussion in the conclusions section of the review of health effects science.

Pg. 9-40, Lines 3-4: To support the concept that distributed lag models provide a more complete effects estimate than single-day lags, reference should be made to key studies such as Schwartz (2000) and Braga et al. (2001) that have examined various single-day as well as distributed lags.

# Dr. Warren H. White

**PM AQCD Chapter 9, rev. 8/04** Comments by Warren H. White, 9/12/04

**Visibility**

I urge something like the following in place of the existing text from line 15, page 9-90 to line 2, page 9-91:

> Airborne particles degrade visibility by scattering and absorbing light. A particle's optical impact is described by its effective cross section for these interactions, which in general is a function of its size and composition. The local intensity of haze is quantified by the concentration of these cross sections in the air (area per volume), called the extinction coefficient (dimension inverse length, or fractional attenuation per distance). The cross sections of distinct particles add, so the extinction coefficient produced by a given distribution of particle sizes and compositions is strictly proportional to the particle mass concentration.
>
> Because the extinction cross section associated with a given mass is much higher for fine particles than for coarse, it is fine-particle mass concentrations that tend to drive extinction coefficients in polluted air. The main source of variation in observed extinction per measured $PM_{2.5}$ is the loss of particle-bound water from ambient particles when they are dried for weighing. In arid regions such as the Southwest, where this effect is minimized, observed extinction/PM2.5 ratios can vary within surprisingly narrow ranges, typically remaining near 2½ +/- ½ $m^2/g$. In more humid areas such as the East, observed cross sections per measured mass are generally higher.

The point is that visibility doesn't just "*depend*" on the mass concentration – it is *linear* with it, and that is a much stronger statement. (Consider how much blood has been spilled over the linearity question for health effects and acid deposition!) Moreover, it is not the "*efficiency*" that depends on particle mass "as modulated by …", but the extinction itself. The extinction *efficiency*, whether referenced to mass, volume, or geometric cross-section, is essentially independent of particle mass concentration, and that is why it is a useful concept.

As noted in the Committee letter, "it would be helpful to indicate the approximate $PM_{2.5}$ mass concentrations that correspond to the various visual range values that are discussed" in the perception/adversity judgment studies. Using the nominal value of 2½ +/- ½ $m^2/g$ given above for the Southwest, it could be noted that the Denver standard corresponds to **short-term** PM2.5 concentrations of **no more than** 20-30 $\mu g/m^3$.

**The distinction of "fine" and "coarse"**

The introductory sentence beginning on line 12 of page 9-8 would be clearer as:

> The evidence available in the last review strongly focused on particle size as the basis for distinguishing two essentially different classes of particles.

I would urge also that "*natural*" and "*a fundamental distinction*" be dropped from the introductory sentence beginning on line 1 of 9-8.

# Dr. George T. Wolff

Comments on Chapter 9

By

George T. Wolff
(9/20/04)

While I think the chapter has improved, it still reflects the Agency's biases for overstating the evidence for PM effects and downplaying the uncertainties.

The document does contain the relevant science except for an objective discussion of the latest information on models specification. I acknowledge the fact that a conscious decision was made at the July meeting to exclude parts of this issue from the discussion. However, as we move on to the Staff Paper, I do not see how we can avoid this discussion.

Starting on page 9-22, I think it is misleading to state that many recent studies "built upon what was previously known" without saying that many, if not most, of the new studies cannot be considered because of the GAM fiasco.

On page 9-23, the top line should be re-worded to say the GAM-related has led to smaller effects in "most" rather than "some" cases.

On the same page, in the bottom paragraph, it should be pointed out that the single-pollutant analysis tends to overestimate the effects because it does not consider the contributions from other factors.

Figure 9-4 presents a distorted view of the risk estimates by hiding the heterogeneity that is present in the NMMAPS results. As a result, the accompanying discussion on 9-26 to 9-30 does not reflect the uncertainty that exist in the data because of the heterogeneity issue.

It should be pointed out that the studies cited on the bottom of page 9-28 and 9-29 that implicate traffic are based mostly on studies that used Pb as a tracer and may have no relevance to current vehicle emissions.

I still disagree with the Agency's interpretation of the long-term exposure studies and their decision to largely ignore the negative results in the VA and AHSMOG studies and the inexplicable results in the ASC and 6 Cities studies. As I pointed out in my previous comments, there are more individuals in the four long-term studies that exhibit no PM effects than those that experience an effect.

Model specification discussion on pages 9-32 and 9-33 – The components of this issue are mentioned, but not put into context. This section has no conclusions. It does not convey the seriousness of this issue.

P 9-43, line 30 to p 9-44, lines 1 and 2 – I do not agree with this sentence. If it remains, it needs a reference. As far as I am aware, the HEI commentary on the revised studies is the most recent statement on this subject and it is in conflict with this sentence.

# NOTICE

This report has been written as part of the activities of the Environmental Protection Agency's (EPA) Clean Air Scientific Advisory Committee (CASAC), a Federal advisory committee administratively located under the EPA Science Advisory Board Staff that is chartered to provide extramural scientific information and advice to the Administrator and other officials of the EPA. The CASAC is structured to provide balanced, expert assessment of scientific matters related to issue and problems facing the Agency. This report has not been reviewed for approval by the Agency and, hence, the contents of this report do not necessarily represent the views and policies of the EPA, nor of other agencies in the Executive Branch of the Federal government, nor does mention of trade names or commercial products constitute a recommendation for use. CASAC reports are posted on the SAB Web site at: http://www.epa.gov/sab.